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H4* *44*

CLAIMS:

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A1*
1. An isolated PHELIX protein having the amino acid sequence as shown in FIG. 2.
- 5 2. An isolated polypeptide of at least 15 contiguous amino acids of the protein of claim 1.
3. An isolated polypeptide which is at least 90% identical to the amino acid sequence of the protein of claim 1 over its entire length.
- 10 4. An isolated polypeptide of at least 15 contiguous amino acids of the protein of claim 3.
- 15 5. An isolated polynucleotide selected from the group consisting of (a) a polynucleotide having the sequence as shown in FIG. 2, wherein T can also be U; (b) a polynucleotide having the sequence as shown in FIG. 2, from nucleotide residue number 735 through nucleotide residue number 1949, wherein T can also be U; (c) a polynucleotide encoding a PHELIX polypeptide whose sequence is encoded by the cDNA contained in the plasmid as deposited with American Type Culture Collection as Accession No. 98956; and (d) a polynucleotide encoding the PHELIX protein of claim 1.
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A2* 20
- 25 6. An isolated polynucleotide which selectively hybridizes under stringent conditions to a polynucleotide according to claim 5.
7. An isolated fragment of a polynucleotide according to claim 5 which is at least 20 nucleotide bases in length.
- 30 8. An isolated polynucleotide which is fully complementary to a polynucleotide according to claim 5.
9. A recombinant expression vector which contains a polynucleotide according to claim 5.
- 35 10. A host cell which contains an expression vector according to claim 9.
11. An isolated polynucleotide according to claim 5, 6, 7 or 8 which is labeled with a detectable marker.

12. A process for producing a PHELIX protein comprising culturing a host cell of claim 10 under conditions sufficient for the production of the polypeptide and recovering the PHELIX protein from the culture.

13. A PHELIX polypeptide produced by the process of claim 12.

14. An antibody which specifically binds to the PHELIX protein of claim 1.

15. A monoclonal antibody according to claim 14.

16. A monoclonal antibody according to claim 15 which is labeled with a detectable marker.

17. A monoclonal antibody according to claim 16, wherein the detectable marker is selected from the group consisting of a radioisotope, fluorescent compound, bioluminescent compound, chemiluminescent compound, metal chelator or enzyme.

18. An Fab, F(ab')₂, Fv or Sfv fragment of a monoclonal antibody according to claim 15.

19. A fragment of a monoclonal antibody according to claim 18 which is labeled with a detectable marker.

20. A fragment of a monoclonal antibody according to claim 19, wherein the detectable marker is selected from the group consisting of a radioisotope, fluorescent compound, bioluminescent compound, chemiluminescent compound, metal chelator or enzyme.

21. A monoclonal antibody according to claim 15 which comprises murine antigen binding region residues and human antibody residues.

22. A monoclonal antibody according to claim 15 which is a human antibody.

23. A transgenic animal producing a monoclonal antibody according to claim 22.

24. A hybridoma producing a monoclonal antibody according to claim 15.

25. A recombinant protein comprising the antigen binding region of a monoclonal antibody according to claim 15.

5 26. A recombinant protein according to claim 25 which is labeled with a detectable marker.

10 27. A recombinant protein according to claim 26, wherein the detectable marker is selected from the group consisting of a radioisotope, fluorescent compound, bioluminescent compound, chemiluminescent compound, metal chelator or enzyme.

15 28. A single chain monoclonal antibody which comprises the variable domains of the heavy and light chains of a monoclonal antibody according to claim 15.

20 29. A vector comprising a polynucleotide encoding a single chain monoclonal antibody according to claim 28.

25 30. An assay for detecting the presence of a PHELIX protein in a biological sample comprising contacting the sample with an antibody of claim 16, an antibody fragment of claim 19, or a recombinant protein of claim 26, and detecting the binding of PHELIX protein in the sample thereto.

30 31. An assay for detecting the presence of a PHELIX polynucleotide in a biological sample, comprising

35 (a) contacting the sample with a polynucleotide probe which specifically hybridizes to the PHELIX cDNA contained within the plasmid as deposited with American Type Culture Collection as Accession No. 98956, or the polynucleotide as shown in FIG. 2, or the complements thereof; and

40 (b) detecting the presence of a hybridization complex formed by the hybridization of the probe with PHELIX polynucleotide in the sample, wherein the presence of the hybridization complex indicates the presence of PHELIX polynucleotide within the sample.

45 32. An assay for detecting the presence of PHELIX mRNA in a biological sample comprising:

(a) producing cDNA from the sample by reverse transcription using at least one primer;

(b) amplifying the cDNA so produced using PHELIX polynucleotides as sense and antisense primers to amplify PHELIX cDNAs therein;

(c) detecting the presence of the amplified PHELIX cDNA,

wherein the PHELIX polynucleotides used as the sense and antisense probes are capable of amplifying the PHELIX cDNA contained within the plasmid as deposited with American Type Culture Collection as Accession No. 98956.

33. A method of detecting the presence of a cancer expressing PHELIX protein which comprises determining the level of PHELIX protein expressed by cells in a test tissue sample from an individual and comparing the level so determined to the level of PHELIX expressed in a corresponding normal sample, the presence of elevated PHELIX protein in the test sample relative to the normal sample providing an indication of the presence of such cancer in the individual.

34. A method of diagnosing the presence of cancer in an individual comprising:

(a) obtaining a test sample of tissue from the individual;

(b) determining the level of PHELIX mRNA expressed in the test sample;

(c) comparing the level so determined to the level of PHELIX mRNA expressed in a comparable known normal tissue sample,

the presence of elevated PHELIX mRNA expression in the test sample relative to the normal tissue sample providing an indication of the presence of cancer.

35. The method of claim 34, wherein the cancer is prostate cancer, and the test and normal tissue samples are selected from the group consisting of prostate tissue, bone tissue, lymphatic tissue, serum, blood or semen.

36. The method of claim 34, wherein the cancer is bladder cancer, and the test and normal tissue samples are selected from the group consisting of bladder tissue, lymphatic tissue, serum, blood, semen or urine.
- 5 37. The method of claim 34, wherein the cancer is ovarian cancer, and the test and normal tissue samples are selected from the group consisting of ovary tissue, lymphatic tissue, serum, blood, semen or urine.
- 10 38. The method of claim 34, wherein the cancer is testicular cancer, and the test and normal tissue samples are selected from the group consisting of testis tissue and semen.
- 15 39. A method of diagnosing the presence of cancer in an individual comprising:
- (a) obtaining a test sample of tissue from the individual;
- (b) determining the level of PHELIX protein expressed in the test sample;
- (c) comparing the level so determined to the level of PHELIX protein expressed in a comparable known normal tissue sample,
- 20 the presence of elevated PHELIX protein in the test sample relative to the normal tissue sample providing an indication of the presence of cancer.
- 25 40. The method of claim 39, wherein the cancer is prostate cancer, and the test and normal tissue samples are selected from the group consisting of prostate tissue, bone tissue, lymphatic tissue, serum, blood or semen.
- 30 41. The method of claim 39, wherein the cancer is bladder cancer, and the test and normal tissue samples are selected from the group consisting of bladder tissue, lymphatic tissue, serum, blood, semen or urine.
- 35 42. The method of claim 41, wherein the cancer is ovarian cancer, and the test and normal tissue samples are selected from the group consisting of ovary tissue, lymphatic tissue, serum, blood, semen or urine.

43. The method of claim 39, wherein the cancer is testicular cancer, and the test and normal tissue samples are selected from the group consisting of testis tissue and semen.
- 5 44. A method of treating a patient with a cancer that expresses PHELIX which comprises administering to said patient a vector according to claim 29, such that the vector delivers the single chain monoclonal antibody coding sequence to the cancer cells and the encoded single chain antibody is expressed intracellularly therein.
- 10 45. The method according to claim 44, wherein the cancer is selected from the group consisting of cancer of the prostate, bladder, ovary or testis.
- 15 46. A method of treating a patient with a cancer that expresses PHELIX which comprises inhibiting the transcription of PHELIX in the cells of said cancer.
- 20 47. The method according to claim 46, wherein PHELIX transcription is inhibited by contacting the PHELIX gene with an antisense polynucleotide complementary to a polynucleotide of claim 5.
- 25 48. A method of treating a patient with a cancer that expresses PHELIX which comprises inhibiting the translation of PHELIX mRNA in the cells of said cancer.
- 30 49. The method according to claim 48, wherein PHELIX mRNA translation is inhibited by contacting the PHELIX mRNA with an antisense polynucleotide complementary to a polynucleotide of claim 5.
50. The method according to claim 48, wherein PHELIX mRNA translation is inhibited by contacting the PHELIX mRNA with a ribozyme capable of cleaving said PHELIX mRNA.
- 35 51. A vaccine composition for the treatment of a cancer expressing PHELIX comprising a PHELIX protein according to claim 1 and a physiologically acceptable carrier.
52. A vaccine composition for the treatment of a cancer expressing PHELIX comprising an immunogenic portion of a PHELIX protein according to claim 2 and a physiologically acceptable carrier.

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